Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13044

5 - SUMMARIES

[redacted]

NAME :	[redacted]	ADMITTED :	08/03/98
AGE :	55	DISCHARGED :	08/05/98
PT.NO. :	[redacted]	PHYSICIAN :	[redacted] M.D.
UNIT :		CONSULTANT :	

DISCHARGE DIAGNOSES:
1. Hepatitis possibly related to over-the-counter diet medication.
2. Chest pain possibly related to same.
3. History of depression.

HISTORY OF PRESENT ILLNESS: The patient is a 55-year-old patient admitted to the hospital for evaluation of chest pain. While in the Emergency Room she was noted to have abnormal liver function test and was admitted for evaluation of these problems. For further details of the history and physical examination see the typed dictated note performed at the time of admission.

LABORATORY DATA: The CBC was normal. A pro-time was normal. Amylase and lipase were normal. The CPK and cardiac enzymes including troponin levels were normal. Cholesterol was 127, HDL 73. Hepatitis A, B, and C antibody testing and antigen testing were negative. Serum ferritin was elevated at 1266. TSH was normal at 3.5. On admission the SGOT was 555, the following day it was 454 and on the day of discharge the SGOT was 204. The alkaline phosphatase on admission was 153, rising to 208 the second day and further increasing to 279 on the day of discharge. The bilirubin on the day of admission was 1.5, increased to 2.5 and then it was down to 0.6 at the time of discharge. Phosphorus was somewhat low on admission but it was normal at the time of discharge as the patient began to eat again. Her albumin was 2.7 on 08/04/98 and was up to 3.1 at the time of discharge. A CT scan of the abdomen was negative. Ultrasound of the abdomen was negative. EKG was normal. Echocardiogram showed no significant abnormalities. The ejection fraction appeared to be normal.

HOSPITAL COURSE: The patient had an uneventful hospitalization. Her liver function test normalized. It was felt likely that she suffered liver injury from an over-the-counter preparation that she bought two weeks prior to admission for weight loss. The name of this medication was Metabolite and included multiple medications as listed in the history and physical examination. It is not known which of these components caused liver injury. She was cautioned not to take this medicine. It is likely that some pathomimetic preparation within this medication caused her chest pain. Her appetite improved, her nausea disappeared, she had no further chest pain and she was feeling much better at the time of discharge as the liver function test normalized.

She will return to the office in two weeks. She will have repeat liver function test done as well as a serum ferritin. She was instructed to stop the Prozac but remain on Trazodone and Premarin. No other prescription given.

[redacted]

D: 08/05/98
T: 08/06/98
set [redacted]

DISCHARGE SUMMARY

(Metabolife follow-up)
Assign. # 98-0215
collected 10/26/98
RDB
Exhibit Z, page #1

[redacted]

Name	: [redacted]	Admitted	: 08/03/98
DOB	: [redacted]	Discharged	:
No	: [redacted]	Physician	: [redacted] M.D.
Unit	: [redacted]	Consultant	:

HISTORY OF PRESENT ILLNESS: Ms. [redacted] is a 55-year-old lady admitted on internal medicine card assignment for evaluation of chest pain and abdominal pain. She was, also, noted to have markedly abnormal liver function tests while in the emergency room.

This patient was in her usual state of health when she experienced rather sharp, severe chest pain located in her mid sternum, radiating directly through to her back. This pain started, as mentioned, the day prior to her coming to the emergency room. She did not sleep well the night following admission. The pain was not aggravated by eating, not aggravated by breathing. There was no cough and no fever. The pain did not seem to be aggravated, also, by positional changes. It was fairly constant and unremitting. She saw a local physician, who gave her some nitroglycerin, but this did not seem to help. She then came to the emergency room and received a cardiac evaluation, which was negative, including an EKG, chest x-ray, and cardiac enzymes. Her O2 saturation was 99%; she denied any shortness of breath. This pain was new, was probably developing two or three days before it got really bad. She was given an injection of Demerol, which greatly reduced her pain.

This patient takes Trazodone 150 mg at bedtime and Prozac probably 40 mg in the morning for treatment of depression. She has been on these stable medications for five years without any difficulty, and her depression has been stable. She has been on estrogen .0625 mg q.d. for several years, as well. She has had no history of deep venous thrombosis or clotting disorders.

Approximately 10 days prior to her admission, while the patient was shopping at the mall, she purchased a diet supplement called Metabolife containing several minerals and guarana concentrate, which is equivalent to 40 mg of naturally occurring caffeine. She, also, was taking a Ma Huang concentrate that is equivalent to 12 mg of naturally occurring ephedrines. Other medications included ginseng, bovine complex, damiana leaves, sarsaparilla root, nettles, goldseal, also, something called kotukola, and spirunina algae. Bee pollen and royal jelly are, also, thrown in. She has been taking three of these a day. When she started developing this chest pain, she stopped the medicine and has been off of it for a couple of days.

Her SGOT in the emergency room was 500, alkaline phosphatase was slightly elevated at 153, the bilirubin was 1.5, phosphorus was 2.4, albumin was 3.4, chlorides were 108. CBC appeared normal. Lipase was normal. Amylase was normal. CPK was normal. Cardiac enzymes were normal. Hepatitis A IgM antibody was negative. She has had no known exposure to hepatitis. She denies having a blood transfusion. No previous history of hepatitis or jaundice.

CONTINUED

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10/26/98 ROB page # 2

[redacted]

[redacted]

HISTORY OF PRESENT ILLNESS Continued

No travel outside the country. She has been eating some seafood, but only within the confines of the [redacted] Other family members have not been ill. She denies any fever, denies jaundice, no urinary tract infections, denies diarrhea. She has had some nausea. Appetite has been off. She has felt stimulated, and her sleep has been somewhat less than ideal, even on the trazodone.

PAST MEDICAL AND SURGICAL HISTORY: Surgeries include a cholecystectomy done at age 25 and a hysterectomy for benign reasons done several years ago. She still has her ovaries. She has had polyps removed from her sinuses. She is gravida 2, para 2, abortus 0. She has had endometriosis in the past. No hospitalizations in the past six years. She denies a significant history of accidents and injuries.

ALLERGIES: None known.

MEDICATIONS:

1. Premarin 0.625 mg q.d.
2. Desyrel 150 mg h.s.
3. Prozac 20 mg two tablets q.d.
4. Baby aspirin just on the day of admission.

FAMILY AND SOCIAL HISTORY: The patient was divorced five years ago and is living with her daughter and granddaughter somewhere in the [redacted] She drinks alcohol occasionally. She does smokes cigarettes, I believe, one-half to one pack a day. Family history is positive for cancer and heart disease.

REVIEW OF SYSTEMS: She has no history of diabetes or thyroid disease. No history of cardiac disease, high blood pressure, or palpitations. No previous cardiac diagnoses without chest pain. No dyspnea on exertion. No cough. No recent virus or febrile illness. She denies asthma and emphysema. No history of pleurisy, pericarditis, skin rash, or arthritis.

She has no history of ulcer disease, dyspepsia, and does not take antacids. There has been no weight loss. In fact, she thinks she has gained weight. Diet fluctuates up and down. Depression is stable. She is not active physically. She does take care of her granddaughter. She has been a homemaker.

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Assign # 98-0215
10/20/98
ROB page 3

[redacted]

[redacted]

PHYSICAL EXAMINATION:

GENERAL: The patient is a pleasant, middle-aged woman in no acute distress.

VITAL SIGNS: Vital signs are normal. She is afebrile.

SKIN: Skin is normal. No jaundice noted.

HEENT: Head, eyes, ears, nose, and throat are normal.

NECK: Thyroid is normal.

LUNGS: Lungs are clear.

CARDIOVASCULAR: Regular rate without murmurs or gallops.o

ABDOMEN: Abdomen is soft. There is a midline scar and a lower abdominal suprapubic scar going horizontally. There is tenderness in the epigastrium and right upper quadrant that is very mild. I cannot really feel the liver edge. There is minimal tenderness in the left upper quadrant. Bowel sounds are present. No adenopathy.

BREASTS: Breasts are not examined. She has had a mammogram and a breast exam two months ago in [redacted] She, also, had a pelvic exam.

MUSCULOSKELETAL: Musculoskeletal examination is normal.

EXTREMITIES: No edema. Good pedal pulses.

NEUROLOGIC: Neurologically, she is awake, alert, and oriented. She moves all four extremities. No obvious cranial nerve signs. She can give a good history.

IMPRESSION:

1. Hepatitis of unknown cause, possibly related to over-the-counter medicines with multiple herbal ingredients, including Ma Huang and guarana and several other medicines as mentioned in the History of Present Illness. Certainly, there are other possibilities here, as well. Could be a viral hepatitis, etcetera.

CONTINUED

EXHIBIT #2
#98-0215
10/26/98
RDB p.#4

[redacted]

[redacted]

IMPRESSION Continued

2. Chest pain, I think, probably related to above, but cannot rule out cardiac disease definitely at this point.

3. Depression, stable, on Trazodone and Prozac.

4. Hormone replacement treatment.

PLAN: Will do an ultrasound of the abdomen and a CT scan. Will check liver function tests and hepatitis C.

[redacted]

D: 08/03/98
T: 08/03/98 [redacted]

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10/26/98
P. #5
RDB

[redacted]

Name: [redacted]
DOB:
No:
Unit:

Admitted: 8/3/98
Discharged:
Physician:
Consultant: [redacted]

DATE OF CONSULTATION: August 5, 1998

HISTORY OF PRESENT ILLNESS: The patient is a 55-year-old woman who is referred by Dr. [redacted] for evaluation of hepatic dysfunction.

The patient has moved here recently from [redacted] The patient had been in stable health without any medical problems until she developed the sudden onset of chest pain, which was in the epigastric area radiating through to the back. The patient came to the emergency room and was admitted.

The chest pain resolved fairly rapidly and has not returned. The patient had had some intermittent difficulty for two to three days prior to admission, but not before that. The patient denies dysphagia, vomiting, change in bowel habits, diarrhea, rectal bleeding, or melena. The patient has not had significant constipation. The patient has not lost weight. The patient has not had any other abdominal pain and she has never had symptoms like this before. The patient has generally been in good health.

MEDICATIONS: The patient had started taking a diet pill from a health food store for approximately two weeks prior to this illness. The patient's other medicines are Desyrel and Prozac, which she has taken for five years without any difficulty. These were prescribed by a physician in [redacted] and the patient is currently using those prescriptions.

The patient has not had any exposure to hepatitis, has not had any previous history of liver disease or hepatitis, and generally has not had any liver problems.

SOCIAL HISTORY: The patient smokes a half a pack a day and does not drink. The patient denies any other medications, mushroom use, exposure to over-the-counter or alternative therapy medicines except for the diet pill. The patient has not used mushroom tea.

PAST MEDICAL AND SURGICAL HISTORY: The past medical history is positive for a cholecystectomy over 20 years ago; a remote hysterectomy.

FAMILY HISTORY: The family history is negative for liver disease.

REVIEW OF SYSTEMS:

GENERAL: The patient denies chest pain suggestive of angina at any other time. The patient has not had shortness of breath, cough, wheezing, hemoptysis, hematuria, dysuria, fever, chills, syncope, neurologic dysfunction, or other acute illness.

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[redacted]

[redacted]

LABORATORY DATA & DIAGNOSTIC STUDIES: The patient's electrocardiogram exam was normal. A CAT scan of the abdomen was normal without dilated bile ducts and the liver looked normal. Ultrasound of the abdomen was also normal and liver and bile ducts were normal by that as well.

Laboratory studies showed: Bilirubin 1.5. Alkaline phosphatase 153. SGOT 555. The next day: Bilirubin 2.5. Alkaline phosphatase 208. SGOT 454. The next day, today: Bilirubin 0.6. Alkaline phosphatase 279. SGOT 204. Albumin 3.1.

TSH 3.5.

Hepatitis B studies A antibody and C antibody were all negative. Ferritin was 1266. Amylase 46. Lipase 219. Hemoglobin 13.9. WBC 6.9. PT 11.6. CK 50. ACP negative.

PHYSICAL EXAMINATION:

HEAD AND NECK: No adenopathy or palpable thyroid.

NECK: The neck is supple.

CHEST: The chest is clear.

CARDIAC: The heart has a regular rate.

ABDOMEN: The abdomen is soft and nontender without organomegaly or mass. Bowel sounds are normal. No bruits are heard. There is no guarding, rebound, rigidity, or ascites. The liver is not enlarged or palpable.

EXTREMITIES: The extremities are negative.

NEUROLOGICAL: The patient is neurologically intact.

IMPRESSION:

1. Hepatic dysfunction, of uncertain etiology. The liver function tests have improved significantly in two days in the hospital and I feel the patient can be followed as an outpatient.
2. Ultrasound, CAT, Hepatitis A, B, and C studies were negative. Ferritin was 1266, which may be elevated and acute hepatic inflammation is difficult to interpret.

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CONTINUED

[redacted]

[redacted]

IMPRESSION: Continued

3. A common duct stone would be unlikely due to the remote gallbladder surgery and negative amylase, lipase, and studies of the bile duct by imaging on this admission.

RECOMMENDATIONS:

1. Would recommend another Ferritin and liver function tests in three to four weeks and have advised the patient to be sure to call if she has any further symptoms or chest pain, and the patient agrees and promises to do so.
2. The patient promises to follow up.

Thank you for referring this patient.

[redacted]

D: 8/5/98
T: 8/5/98 [redacted]

cc: [redacted] M.D.

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CONSULTATION